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| 09/466,971      | 12/20/1999  | MICHEL CALLUAUD      | 38730.830029        | 1797             |

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT

PAPER NUMBER

3761

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

**RECEIVED**  
PILLSBURY WINTHROP LLP/VA

JAN 25 2002

CL 74066 MT# 270804  
ATTY(S) GJP MGP  
DUE: 01-17-02  
DKT BY (1) CMS (2) JAH

## Office Action Summary

|                 |              |              |                |
|-----------------|--------------|--------------|----------------|
| Application No. | 09/466,971   | Applicant(s) | Callaud et al. |
| Examiner        | Joseph Weiss | Art Unit     | 3761           |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Dec 20, 1999

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-5, 7-31, and 33-49 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-5, 7-31, and 33-49 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. **RECEIVED**

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**JAN 25 2002**

### Attachment(s)

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18)  Interview Summary (PTO-413) Paper No(s). 41D MT# 270804

19)  Notice of Informal Patent Application (PTO-152) DUE: 04-07-02 DKT BY(1) CMS (2) 1, ln

20)  Other:

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## DETAILED ACTION

### *Specification*

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally **limited to a single paragraph** on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The disclosure is objected to because of the following informalities: the above bolded informalities relating to the abstract of the disclosure.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. Claims 1, 6-11, 14 & 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-11 are indefinite because it is unclear if applicant is claiming the combination of a Substance delivery apparatus and a "system for supplying a breathable gas" or the subcombination of a substance delivery apparatus. This lack of definiteness arises from the clear

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indication in the preamble that the applicant intends to claim only the above subcombination, but applicant goes on in the claims to positively recite the combination.

The lack of consistency between the preamble and a portion or the portions of the body of the claims renders the claims indefinite, because the scope of the claim is unclear. Applicant is required to clarify to what the claim is intended to be drawn, i.e. either the combination or the subcombination, and further that the language of the claims be made consistent with this intent.

The claims are being considered as having been drawn to the combination. If indicated by amendment that the combination claim is the intention, the language in the preamble should be made consistent with the language in the body of the claims. If indicated that the intent is to claim the subcombination only, the body of the claim must be amended to remove any positive recitations of the combination.

4. Claim 1 recites the limitation "the supplied breathable gas" in 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 1 recites the limitation "the substance" in 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 1 recites the limitation "the inhalation" in 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 1 recites the limitation "the supplied pressure" in 7 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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In regards to claim 14, the claim sets forth a "second amplifier" however it is unclear whether or not the invention consists of one amplifier or two amplifiers since no previous amplifier has been introduced into the invention of claim 14.

8. Claim 27 recites the limitation "the supplied breathable gas" in 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 27 recites the limitation "the substance" in 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 27 recites the limitation "the inhalation" in 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 27 recites the limitation "the supplied pressure" in 7 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In regards to both claims 1 & 27 the claims are further rendered indefinite by use of the term "amount" in the last line because it is unclear as to what applicant is referring to by use of the term.

In regards to claim 44, line 1 it states "A method as claimed in any one of claim 43" appears to be a typographical error but renders the claim indefinite since it is unclear whether claim 44 is solely dependent on claim 43 or is a multiple dependent claim. The examiner will examine the claim as if it were dependent only upon claim 43.

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12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

13. Claims 1-4 & 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Briend et al (US 5651358).

In regards to claims 1 & 27, Briend discloses an apparatus/method for delivering a substance for use with a ventilator system wherein the apparatus comprises a means to continuously measure the pressure of supplied breathable gas (15, 16 & 17), a means to detect inhalation by the user (same elements note col. 2 lines 35-40), and a means to deliver a substance to the user (18) during inhalation at a pressure that exceeds the measured pressure of the supplied air's pressure by a predetermined amount. (Col. 2 lines 43-50).

In regards to claims 2 & 28, Briend discloses the use of a medical substance, Nitric Oxide.

In regards to claims 3 & 29, Briend discloses the substance being in the form of a gas.

In regards to claims 4 & 30, Briend discloses delivery of the substance to a user's respiratory tract.

*Claim Rejections - 35 USC § 103*

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5, 13-14 & 31, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briend.

In regards to claims 5, the reference noted above substantially disclose the claimed invention except for the delivery of the substance to the nasal cavity of the mammal.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this feature to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 13, Briend discloses a pressure transducer that generates a signal indicative of the pressure in the conduit.

In regards to claim 14, the reference noted above substantially disclose the claimed invention except for the use of a second amplifier.

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It is noted that applicant's specification does not set forth the use of an amplifier, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of an amplifier to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 31, 37-38, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 5, 13-14.

16. Claims 15-22 & 39-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briend in view of Bolt et al. (DE 19525557 A1).

In regards to claims 15-20 & 22 which set forth a positive displacement pump in the form of a diaphragm pump, with a linear drive means and an electric motor with a rotary to linear converter driven by a rotary drive means and in fluid communication with a reservoir and breathing conduit via one way valves, Briend substantially disclose the claimed invention except

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for the diaphragm pump with an electric motor as a rotary to linear in fluid communication with a reservoir and breathing conduit via one way valves. However, Bolt disclose such features in a dosing apparatus (linear drive means 5, rotary drive means 7 which together function as the rotary to linear drive means, diaphragm 6 & one way valve in communication with a reservoir & conduit 17/21). The references are analogous since they are from the same field of endeavor, the dosing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Bolt and used them with the device of Briend. The suggestion/motivation for doing so would have been to facilitate a more precise dosing to a user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 21, use of an electro-magnet as a linear drive means, the suggested device substantially discloses such except for this feature.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the applied reference.

Accordingly, the examiner considers the selection of this feature to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the applied art.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to

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the contrary. (See Col. 1 lines 7-17 of US 5971723, the English language version of the Bolt reference.)

In regards to method claims 39-49, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 15-22.

17. Claims 7-12 & 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briend in view of Eichler (US 4588710) & Snook et al (4938212).

In regards to claims 7-12, Briend substantially discloses the instant application's invention to include the use of a pressurized gas flow generator (1) in fluid communication with a patient and an inhalation/exhalation detection means for detecting the inhalation/exhalation flow of the patient in the conduit (15/16) and generating the respective signals indicative of the breathing gas inhalation/exhalation flow rate (note connectivity to electronic controller 17, col. 2 lines 30-35) but does not disclose the use of a pressure sensor/flow resistance element to determine breathing gas flow rate and pressure. But Eichler discloses such (element 16 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory dosing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Eichler and used them with the device of Briend. The suggestion/motivation for doing so would have been to use a direct in line

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monitoring of pressure to produce a more accurate/real time pressure reading. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. But the suggested device does not disclose the use of an air flow sensor adapted to detect the volumetric flow rate of the breathing gas nor does the suggested device disclose the use of amplifiers to amplify the signals sent by the sensors indicative of flow. However, Snook discloses the use of amplifiers to amplify sensor signals (Fig 1, "Inhalation Sensor" Columns 18 & 19, specifically Col. 18 line 64-Col. 19 line 54) and Snook discloses the equivalency of a pressure sensor with a volume based air flow sensor (Col. 2, line 61-Col. 3, line 18)

Briend & Eichler and Snook are analogous art because they are from the same field of endeavor, the respiratory arts. At the time of the instant application's invention it would have been obvious to one of ordinary skill in the art to have used a volumetric air flow sensor and electronic signal amplifier and used it in the device of Briend & Eichler in light of the teachings of Snook regarding the equivalency of sensors and use of electronic signal amplifiers with sensors. Thus resulting in the invention of the instant claims.

In regards to the flexible conduit terminating in a mask, with a vent, to interface with the respiratory system of a patient, the references noted above substantially disclose the claimed invention except for the flexible conduit terminating in a mask, with a vent, to interface with the respiratory system of a patient.

It is noted that applicant's specification does not set forth the flexible conduit terminating in a mask, with a vent, to interface with the respiratory system of a patient as unexpectedly

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providing any new result or unexpectedly solving any new problem in the art over the applied reference.

Furthermore, given the current skill level in the art, one of ordinary skill would consider the use of a flexible conduit terminating in a mask, with a vent, to interface with a patient's respiratory system to be common knowledge in the art.

Accordingly, the examiner considers the selection of a flexible conduit terminating in a mask, with a vent, to interface with the respiratory system of a patient to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the applied art.

In regards to method claims 33-36, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 7-12.

#### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b):

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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19. Claims 1-5, 7-31, 33-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6029660 in view of Briend.

'660 substantially discloses the instant application's claimed invention, but does not explicitly disclose-claim an apparatus/method for delivering a substance for use with a ventilator system wherein the apparatus comprises a means to continuously measure the pressure of supplied breathable gas, a means to detect inhalation by the user and a means to deliver a substance to the user during inhalation at a pressure that exceeds the measured pressure of the supplied air's pressure by a predetermined amount. However, Briend disclose such (See elements 15-18 & col. 2 lines 35-50. The references are analogous since they are from the same field of endeavor, the respiratory arts . At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Briend and used them with the device of '660. The suggestion/motivation for doing so would have been to generate a more accurate dose of substance for entrainment into a ventilator flow for delivery to a user's pulmonary system. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

### *Conclusion*

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5971723, 5845633, 5839433, 5497944, 4375346, 4307730, 4210136, 4155356, 4141355 WO 97/03290

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19. Claims 1-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6029660 in view of Briend. '660 substantially discloses the instant application's claimed invention, but does not explicitly disclose-claim an apparatus/method for delivering a substance for use with a ventilator system wherein the apparatus comprises a means to continuously measure the pressure of supplied breathable gas, a means to detect inhalation by the user and a means to deliver a substance to the user during inhalation at a pressure that exceeds the measured pressure of the supplied air's pressure by a predetermined amount. However, Briend disclose such (See elements 15-18 & col. 2 lines 35-50. The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Briend and used them with the device of '660. The suggestion/motivation for doing so would have been to generate a more accurate dose of substance for entrainment into a ventilator flow for delivery to a user's pulmonary system. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

### *Conclusion*

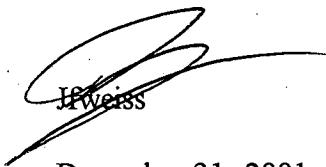
20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5971723, 5845633, 5839433, 5497944, 4375346, 4307730, 4210136, 4155356, 4141355 WO 97/03290

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Joseph F. Weiss, Jr.**, whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, **John G. Weiss**, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



JF Weiss  
December 31, 2001